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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,400	12/27/2000	Thomas Specht	SCH-1779	7219

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EXAMINER	
KATCHEVES, KONSTANTINA T	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,400	SPECHT ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-22 and 27-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-40 are pending in the present application. Claims 1-22 and claims 27-40 have been withdrawn from consideration as being drawn to a separate and distinct invention. Accordingly, claims 23-26 are pending in the present application.

Response to Arguments

Claims 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record. The rejection of claim25 has been withdrawn as being in error. Applicant is thanked for pointing out the confusion and inconsistency in the rejection. Applicant's arguments are addressed as they pertain to claims 24 and 26.

In response to the pending rejection Applicant argues:

> Claims 24 and 26, which recite a % homology, also include an associated functional activity. One of ordinary skill in the art, using conventional techniques in modern molecular biology, would be able to construct polypeptides having sequences which are 80% or 90% homologous to the polypeptide of SEQ ID NO: 38 and possess the associated function identified as a human mRNA putatively prenylated protein, as described for the encoding SEQ ID NO: 16. . . . One of ordinary skill in the art, using conventional techniques or assays would be able to ascertain that the polypeptides having 80 or 90% homology have the associated functional activity.

Applicant asserts generally that the claims are drawn to sequences having 80 percent or 90 percent homology and recite the associated function as "human mRNA putatively prenylated protein," and are, thus, adequately described.

Regarding the asserted function, MPEP 2163(I)(A) clearly addresses this issue and states:

> A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function." See *University of California v. Eli Lilly and co.* 119 F.3d 1559, 43 USPQ2d 1398 (1997) ("*Lilly*").

Applicant broadly states that the protein functions as a human mRNA putatively prenylated protein." First, it appears that Applicant is stating what they think protein is not what it does. Second, even if "human mRNA putatively prenylated protein" described a function, MPEP 2163(I)(A) and *Lilly* teach that the recitation of functional characteristics without more is not enough. Applicant must disclose the correlation between structure and function. Applicant has disclosed that the sequences have either 80 percent or 90 percent homology with SEQ ID NO:38 but not how the vast number of sequences with the claimed degree of homology relates structurally with the purported function of the protein. Thus, Applicant has not specifically defined any of the proteins that fall within the broad genus claimed nor does Applicant describe any structural characteristics commonly possessed by members of the genus such that one of skill in the art would recognize that Applicant was in possession of the full breadth of the invention claimed.

Claims 23-26 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted and substantial utility for the reasons of record and those set forth below.

Regarding the present rejection, Applicant asserts that:

> As explained in the specification, the claimed polypeptides are coded for by a nucleic acid which is overexpressed in uterus myometrium tumor tissue and therefore can be used, e.g., as diagnostic markers and disease targets. SEQ ID NO:38 which is coded for by SEQ ID NO: 16 (page 57 of the specification) is shown on page 33 as being expressed at higher levels in uterus myometrium tumor tissue as compared to normal uterus myometrium tissue.

Applicant's has pointed to the Northern results on page 33 of the specification in support of the argument that the overexpression of claimed sequence in myometrium cells is a diagnostic for cancer. Thus, this function is asserted as a sufficient specific asserted utility to satisfy the Utility requirement of 35 U.S.C. 101. Upon consideration of the disclosure of the table of Northern results for SEQ ID NO:16 which encodes SEQ ID NO:38, Applicant's data does not indicate a specific utility for the present claims. The data show that bladder cells, endocrine tissue cells, gastrointestinal cells, brain cells, testicular cells, stomach-esophogeal cells, pancreatic cells, penis cells, and uterus myometrium cells, all, display overexpression of SEQ ID NO:16 in tumor cells as compared to normal cells. Because overexpression is evident in a number of unrelated cell types based on Applicant's data, a *specific* credible utility is not established. At best Applicant has merely identified which cells express which ESTs by comparing expression patterns of ESTs from the LifeSeq database, but has not established what their function or use such that the invention is not in readily available form such that a vast

amount of further experimention on the protein itself would be required before it could be used. See e.g. *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966).

Applicant also quotes from page 468 of Molecular Biology of the Cell in support of the position:

> "transcription (transcriptional control) usually predominates" in "the pathway from RNA to protein," leading to the reasonable expectation that overexpression of the RNA would lead to overexpression of the corresponding protein. Thus, polypeptides of SEQ ID NO:38 would be useful as diagnostic markers for uterus myometrium cancer.

Applicant does not consider the full context of the quote from the above text which states that there are genes which are transcribed at a constant level and are modulated solely by posttranscriptional regulatory processes. Therefore, Applicant does not fully acknowledge the teachings of the cited text that over expression of mRNA does not necessarily lead to over expression of the corresponding protein such that even if SEQ ID NO:38 were expressed only in myometrial cells it would not necessarily be useful as a diagnostic marker for cancer.

Additionally, Applicant cites the *Utility Guidelines* at pages 69 and 70 where a merker for cancer has a well-established utility. First, the use of SEQ ID NO:38 as a diagnostic marker for uterus myometrium cancer is not recognized, immediately apparent or specifically asserted in the specification. Second, MPEP 2107.01 states that a general statement of a diagnostic utility would be insufficient. Applicant's specification teaches the use of the proteins as tools for finding active ingredients against cancer, as pharmaceutical agents, or for the production of pharmaceutical agents. Applicant has not pointed to any disclosure in the specification of the asserted utility of SEQ ID NO:38 as a diagnostic marker for uterus myometrium cancer. Although Applicant states that the

sequence is useful as a diagnostic tool for uterus myometrium cancer, Applicant must "reasonably correlate" that activity to a disease condition. Since Applicant has not established any specificity to the claimed sequence, Applicant has failed to meet the utility requirement.

Thus, the present claims stand rejected under the utility requirement of 35 U.S.C. 101

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves

JAMES KETTER
PRIMARY EXAMINER